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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/079,834 05/15/98 MOUNTZ

J D6005

EXAMINER

HM22/0421

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TUNG, M	
ART UNIT	PAPER NUMBER

1644

DATE MAILED:

04/21/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/079,834**

Applicant(s)  
**Mountz And Zhou**

Examiner  
**Mary Tung**

Group Art Unit  
**1644**



☒ Responsive to communication(s) filed on Feb 1, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1, 3-6, and 8-17 is/are pending in the application.

Of the above, claim(s) 10-15 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 3-6, 16, and 17 is/are rejected.

☒ Claim(s) 8 and 9 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

**DETAILED ACTION**

***Election/Restriction***

*In light of the paper filed 2/1/99 (Papers No. 5 and 6), only the following rejections remain:*

***Claim Rejections - 35 USC § 102***

1. Applicant's arguments filed 2/1/99 have been fully considered but they are not persuasive.
2. Claim 17 stands rejected under 35 U.S.C. 102(e) as being anticipated by Bellgrau (US Patent #5,759,536), for the same reasons set forth in the action mailed 10/27/98 (Paper No. 4).
3. The applicants argue that the '536 patent, the donor organ tissue and the Fas ligand are introduced to the recipients through different routes and at different times. However, claim 17 does not recite a specific order in which the donor tissue and the Fas ligand are to be administered. Therefore, the reference teaching anticipates the claimed invention and the rejection is maintained.

***Claim Rejections - 35 USC § 103***

4. Claims 1, 3-6 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bellgrau (US Patent No. 5,759,536) in view of Süss (Z), for the same reasons set forth in the action mailed 10/27/98 (Paper No. 4).
5. The applicants argue that Süss (Z) does not teach or suggest a method of using antigen presenting cells expressing Fas ligand to induce systemic tolerance to an antigen in an individual. The applicants repeated their arguments concerning the '536 patent, discussed, *supra*. However, Süss teaches that CD8<sup>+</sup> dendritic cells express Fas ligand and induces apoptosis of CD4<sup>+</sup> T cells which results in the down regulation of the immune response. Since CD8<sup>+</sup> dendritic cells are well known in the art to be antigen presenting cells, Süss (Z) teaches a method of using antigen presenting cells to induce tolerance to an antigen (FERFEIFPK peptide (see page 1790, col 1, paragraph 3)). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use Fas-ligand-expressing dendritic cells, taught by Süss in the method of antigen-specific immunosuppression in order to improve transplantation success or for the treatment of an autoimmune disease such as diabetes, as taught by the '536 patent (see the abstract and col. 3, lines 51-55, in particular). From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claims 1, 3-6 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bellgrau (US Patent No. 5,759,536) in view of Schuler (Y), for the same reasons set forth in the action mailed 10/27/98 (Paper No. 4).

7. The applicants argue that Schuler (Y) is a review article which does not demonstrate a method of inducing antigen-specific systemic tolerance by administering antigen presenting cells expressing Fas ligand and the antigen. The applicants repeated their arguments concerning the '536 patent, discussed, *supra*. Bellgrau has been discussed, *supra*. However, Schuler teaches that dendritic cells express Fas ligand and may provide a novel approach to induce tolerance in transplantation and autoimmunity (see the abstract, page 320, col. 2, paragraph 2, and page 321, col. 2, in particular). Dendritic cells are well known in the art to be antigen presenting cells. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use Fas-ligand-expressing dendritic cells, taught by Schuler in the method of immunosuppression taught by the '536 patent in order to induce tolerance for the treatment of transplantation or autoimmune disease such as diabetes, as taught by Schuler. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

*The following are new grounds for rejection:*

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bellgrau (US Patent No. 5,759,536) in view of Süss (Z).

9. Bellgrau, et al. (US Patent No. 5,759,536) teaches a method of inhibiting T-lymphocyte-mediated immune responses by providing a recipient animal with Fas ligand or cells expressing Fas ligand. The '536 patent additionally teaches the use of said method to improve organ transplantation and to treat juvenile diabetes (see the abstract, col. 3, lines 42-55, col. 6, lines 64-68 and claims 1-3 and 7, in particular). However, the '536 patent does not teach the use of antigen presenting cells to express Fas ligand in said method. However, Süss teaches that CD8<sup>+</sup> dendritic cells express Fas ligand and induces apoptosis of CD4<sup>+</sup> T cells which results in the down regulation of the immune response. Süss also teaches that the expression of Fas ligand by cell of the anterior chamber of the eye and Sertoli cells provide for the killing of Fas expressing T cells and thus makes these tissues immune-privileged sites. Süss

additionally teaches that the same mechanism probably occurs with dendritic cells and that whole animal models are needed to assess the relative importance of different Fas-ligand expressing cells in controlling immune responses (see the abstract, page 1792, col. 2, paragraph 3, page 1793, and page 1795, in particular). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use Fas-ligand-expressing dendritic cells, taught by Süss in the method of immunosuppression taught by the '536 patent in order to improve transplantation success or for the treatment of an autoimmune disease such as diabetes, as taught by the '536 patent (see the abstract and col. 3, lines 51-55, in particular). From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bellgrau (US Patent No. 5,759,536) in view of Schuler (Y).
11. Bellgrau has been discussed, *supra*. However, the '536 patent does not teach the use of antigen presenting cells to express Fas ligand in said method. However, Schuler teaches that dendritic cells express Fas ligand and may provide a novel approach to induce tolerance in transplantation and autoimmunity (see the abstract, page 320, col. 2, paragraph 2, and page 321, col. 2, in particular). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use Fas-ligand-expressing dendritic cells, taught by Schuler in the method of immunosuppression taught by the '536 patent in order to induce tolerance for the treatment of transplantation or autoimmune disease such as diabetes, as taught by Schuler. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.
12. The article by Chen and Wilson, provided by the applicants with Paper Nos. 5 and 6, is not persuasive, because even though the authors discussed the "ingenuity" of the invention, does not provide evidence that the cited teachings of Süss (Z) and Schuler (Y) do not encompass the claimed invention.

***Allowable Subject Matter***

13. Claims 8 and 9 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

14. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6 pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

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April 20, 1999  
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ART UNIT 182-1644